

REMARKS**Status of the claims**

Claims 1-9, 11, 13, and 15-24 are pending in the application. Claims 1-9, 11, 13, and 15-24 stand rejected.

Claim 1 is amended. No new matter has been added.

Amendments to the claims

Claim 1 has been amended to incorporate the limitation of claim 21. The currently amended claim 1 now has the additional step of "controlling the affixing of said substrate(s) via feedback monitoring of a property of said susceptor, said energy or a combination thereof." The amendment is directly supported by the specification (instant specification, para 0042) and is intended to overcome the 35 U.S.C. §102 rejection.

The 35 U.S.C. §102 rejection

Claims 1-9, 13 and 15-20 are rejected under 35 U.S.C. §102(b) as being anticipated by **Gordon** (U.S. Patent 4,889,120). The Applicants respectfully traverse this rejection.

Regarding claims 1-5, the Examiner states that **Gordon** discloses a method of treatment for one or more tissue substrates in an individual, comprising: securing the tissue substrates proximal to a ferromagnetic metal susceptor; applying radiofrequency energy that generates a magnetic field to said substrate(s) or to said susceptor or to a combination thereof to inductively generate heat therein; and affixing said substrates together via said heat thereby effecting treatment.

Regarding claims 6 and 7, the Examiner states that **Gordon** discloses that the substrates may be further secured by a surgical fastener in the form of 2 to 3 sutures.

Regarding claims 8-9, 13, 15-19 and 20, the Examiner states that **Gordon** discloses the claimed invention. The Applicants respectfully disagree.

Applicants respectfully submit that **Gordon** teaches a method of creating connections between blood vessels and other biological structures comprising: application of electromagnetic energy to generate heat and alter intracellular particles within the edges of biological structures as well as the edges of biological structures with the purpose to connect the biological structures. **Gordon** describes the use of artificially introduced particles which react with an applied electromagnetic field to generate heat sufficient to connect the biological structures. **Gordon** teaches the use of electromagnetic field at the fixed frequency of 400 kHz, or treating particles with a laser beam with the wavelength within the spectrum of visible light.

Applicants have amended independent claim 1 to incorporate the additional step of "controlling the affixing of said substrate(s) via feedback monitoring of a property of said susceptor, said energy or a combination thereof." The Applicants respectfully submit that claim 1 is no longer anticipated as **Gordon** makes no mention of controlling the affixing of the substrates by feedback monitoring. In view of the claim amendment, the Applicants respectfully request that the rejection of claims 1-9, 13, 15-20 under 35 U.S.C. §102 be removed.

The 35 U.S.C. §103 rejection

Claim 11 is rejected under 35 U.S.C. §103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120) in view of Aida *et al.* (U.S. Patent 5,897,495). The Applicants respectfully traverse this rejection.

The Examiner states on page 3 of the Office Action that Gordon discloses the claimed invention except for explicitly reciting pulsed radio frequency energy. The Examiner asserts that it is well known in the art that radio frequency may be applied in continuous duration or in discreet pulses. Furthermore, the Examiner states that Aida *et al.* disclose a system and method of heat-treating tissue and teach "a transmitter coil for transmitting radio frequency pulses to the treatment target portion such that the thermal treatment can be applied to the treatment target portion by the heat induced by the radio frequency pulses." Thus, the Examiner concludes, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Gordon, as taught by Aida *et al.*, to provide radio frequency energy in pulses in order to heat-treat tissue. The Applicants respectfully disagree.

The Applicants respectfully submit that Aida *et al.* disclose a system and method of applying ultrasonic waves to treatment targets such as tumors, calculi, etc. inside a living body, under the guidance of magnetic resonance imaging (MRI). While the invention described by Aida *et al.* focus primarily on treating its targets by the mechanical force of the waves, it does briefly mention that a transmitter coil may be used to apply thermal treatment.

In order for an obviousness rejection to be valid, the combined references must specifically teach each and every element of the claimed invention. Furthermore, the references must provide a reasonable expectation of success and a motivation to combine the teachings. The Applicants respectfully submit that Aida *et al.* do not teach or suggest using their invention to affix tissues. On the contrary, Aida *et al.* specifically teach away from the claimed invention since the heat generated by their devices are used to destroy the targeted area. Furthermore, Aida *et al.* do not disclose the specific susceptors disclosed in Gordon.

Gordon recites particles which may be placed at the edges of the tissues. Aida et al. only recite a coil which may be used to thermally destroy cells/tissues. By comparison, the instant specification specifically teach that the pulsed frequencies prevent overheating of the substrates. There is no similar consideration for Aida et al. since the goal of their invention is to destroy the targeted area. Thus, there is no motivation for one of ordinary skill to combine the Gordon and Aida et al.

In view of the arguments presented herein, the Applicants respectfully request that the rejection of claims 11 under 35 U.S.C. §103 be removed. The Applicants believe that claim 11 is now in condition for allowance.

Claims 21 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Gordon (U.S. Patent 4,889,120), in view of Sawyer (U.S. Patent 5,824,015) in further view of Hedge et al. (U.S. Patent 6,656,174). The Applicants respectfully traverse this rejection.

The Examiner states that Gordon discloses the claimed invention except for explicitly reciting controlling the affixing of said substrates via feedback monitoring of a property of said susceptor, said energy or a combination thereof, wherein said property is heat, an electrical property, eddy currents, conductivity, or frequency changes or a combination thereof. The Examiner asserts that it is well known in the art that the connection of different portion of biological tissue can be effected by the crosslinking of collagen, wherein two portions of biological tissue are place in abutment with each other and heated by various means including laser, RF, microwave, resistive heating, etc. The Examiner further states that Saywer discloses a method for welding biological tissue and teaches that it is well known in the art to denature collagen containing substances and/or tissues by heating the substances and/or tissues to a temperature of 45°C to 75°C in order to form tissue welds/seals.

Additionally, the Examiner states that Hedge et al. disclose method for heat treating biological tissue with RF energy and teach "the interior electrodes 48 and temperature

sensing elements 26 are electrically coupled to the respective RF generator 18 and controller 19, allowing RF power to be delivered to the inflatable chambers 36, and thus, the targeted tissue, under temperature-feedback control." Thus the Examiner concludes, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the invention of **Gordon**, as taught by **Sawyer**, to provide a particular heating temperature range for the treated tissue site in order to achieve collagen crosslinked tissue seal/weld, and as further by **Hedge et al.**, to provide the system with temperature sensors and temperature-feedback control in order to obtain and maintain a particular tissue treatment site temperature. The Applicants respectfully disagree.

The Applicants respectfully submit that **Sawyer et al.** teach a method for joining cylindrical biological structures, comprising drawing ends of the cylindrical biological structures together, placing weldable material over the ends wherein the weldable material is collagen, gelatin, albumin, fibrin or elastin, and applying energy to the weldable material while the ends of the cylindrical biological structures remain drawn together, denaturing or melting the weldable material and adjacent biological structures with the applied energy to cause mixing of the denatured or melted weldable material and adjacent biological tissue, thus joining or restructuring the biological structures col 12, lines 22-36). **Sawyer et al.** teach the use of a patch or a bridge structure formed from any of the proteins listed *supra* to weld cylindrical biological structures with a laser beam by melting the parts of both, patch (bridge) and ends of cylindrical biological structures when they are secured by mechanical support, to achieve fusion.

The Applicants respectfully submit that **Hedge et al.** teach device and method for creating circumferential lesions in and around veins, coronary vessels and other parts of the body without obstructing blood flow. In one particular embodiment, **Hedge et al.** disclose a catheter device which comprise interior electrodes and temperature sensing elements that are electrically coupled to an RF generator and controller, allowing RF power to be delivered to the targeted tissue under temperature-feedback control.

In order for an obviousness rejection to be valid, the combined references must specifically teach each and every element of the claimed invention. Furthermore, the references must provide a reasonable expectation of success and a motivation to combine the teachings. The Applicants respectfully submit that **Hedge et al.** primarily teach the use of their invention to create lesions in blood vessels without obstructing blood flow. As such, any application of heat is used to destroy the targeted area and expressly teach away from the claimed invention. Furthermore, there is no hint or suggestion that their device may be used to monitor the affixing of tissues nor do **Sawyer** and **Hedge et al.** teach the use of susceptors as disclosed in **Gordon**. Thus, there is no motivation for a person of ordinary skill in the art to combine the teaching of **Hedge et al.** with the teachings of **Gordon** and/or **Sawyer**.

In view of the arguments presented herein, the Applicants respectfully request that the rejection of claims 21 and 22 under 35 U.S.C. §103 be removed. The Applicants believe that the claims are now in condition for allowance.

Claims 23 and 24 are rejected under 35 U.S.C. §103(a) as being unpatentable over **Gordon** (U.S. Patent 4,889,120) in view of **Sawyer** (U.S. Patent 5,824,015) and in further view of **Hedge et al.** (U.S. Patent 6,656,174) and still in further view of **Eggers et al.** (U.S. Patent 5,366,443). The Applicants respectfully traverse this rejection.

The Examiner states that **Gordon** in view of **Sawyer** in further view of **Hedge et al.** disclose the claimed invention except for heat is monitored via infrared optical detection. The Examiner asserts that it is well-known in the art to provide temperature sensors in various alternate/equivalent means such as thermistors and infrared optical sensors, for example. The Examiner further states that **Eggers et al.** disclose a medical device and method and teach "temperature sensing may be achieved using fiber optics with infrared sensing technique, a thermocouple, a thermistor or other temperature sensing means." Thus, the Examiner concludes, at the time of the invention, it would have been obvious to one of ordinary skill in the

art to modify the invention of **Gordon** in view of **Sawyer** in further view of **Hedge et al.**, as taught by **Eggers et al.**, to provide the device and system with fiber optics with infrared sensing technique in order to provide specific example of temperature sensing means.

The Applicants respectfully submit that **Eggers et al.** disclose method and apparatus for advancing catheters through occluded body lumens. In one particular embodiment, **Eggers et al.** briefly mention a catheter system having a means for measuring temperature including using fiber optics with infrared sensing, thermocouple, a thermistor, etc.

In order for an obviousness rejection to be valid, the combined references must specifically teach each and every element of the claimed invention. Furthermore, the references must provide a reasonable expectation of success and a motivation to combine the teachings. The Applicants respectfully submit that **Eggers et al.** teach using thermal heating to lower the mechanical strength of occluded areas so that the catheter system may bore through plaque, expressly teaching away from the claimed invention which affixes tissues. Thus, a person of ordinary skill in the art would not be motivated to combine the teaching **Eggers et al.** with the teachings of **Gordon**, **Sawyer** and/or **Hedge et al.**

In view of the arguments presented herein, the Applicants respectfully request that the rejections to claims 21-22 and 23-24 under 35 U.S.C. §103 be removed. The Applicants believe that the claims are now in condition for allowance.

This is intended to be a complete response to the Office Action, mailed December 31, 2008. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution.

Respectfully submitted,

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